

Exhibit I



DEA Trends & Update

San Juan, Puerto Rico Pharmacy Diversion Awareness Conference

March 26-27, 2017



The United States Department of Justice

Drug Enforcement Administration

Luis Carrion
Staff Coordinator
Liaison and Policy Section
Diversion Control Division





Housekeeping

Welcome to the Pharmacy Diversion Awareness Conference (PDAC)

- (San Juan, PR)
- 88th PDAC (Sunday, March 26th); 89th PDAC (Monday, March 27th)
- Please silence **cell phones**
- **NO VIDEO/AUDIO RECORDING**
- **RESTROOMS**
- **CPE Codes**
 - Codes will be provided at the end of each presentation block
 - Due by **Thursday May 25th, 2017 by 11:59pm CDT**
 - Don't forget to complete your evaluations
 - Please wait to register until Monday
 - In about 3 weeks, presentations will be available
- **PARKING**
- **LUNCH:** On-site restaurants / Other options within walking distance
- **COFFEE:** On-site options



Disclosure:

I have no relevant personal/professional/financial relationship(s) to disclose



Goals and Objectives

- Public Health Epidemic
- Drugs of Abuse
- From Pharmaceuticals to Heroin
- Violence
- Indiscriminate Prescribing
- Criminal Activity
- Legal Obligations of DEA Registrants
- DEA's Mission and Response
- Drug Disposal



Data Brief 273: Drug Overdose Deaths in the United States, 1999–2015

Data table for Figure 5. Percentage of drug overdose deaths involving selected drug categories: United States, 2010, 2014, and 2015

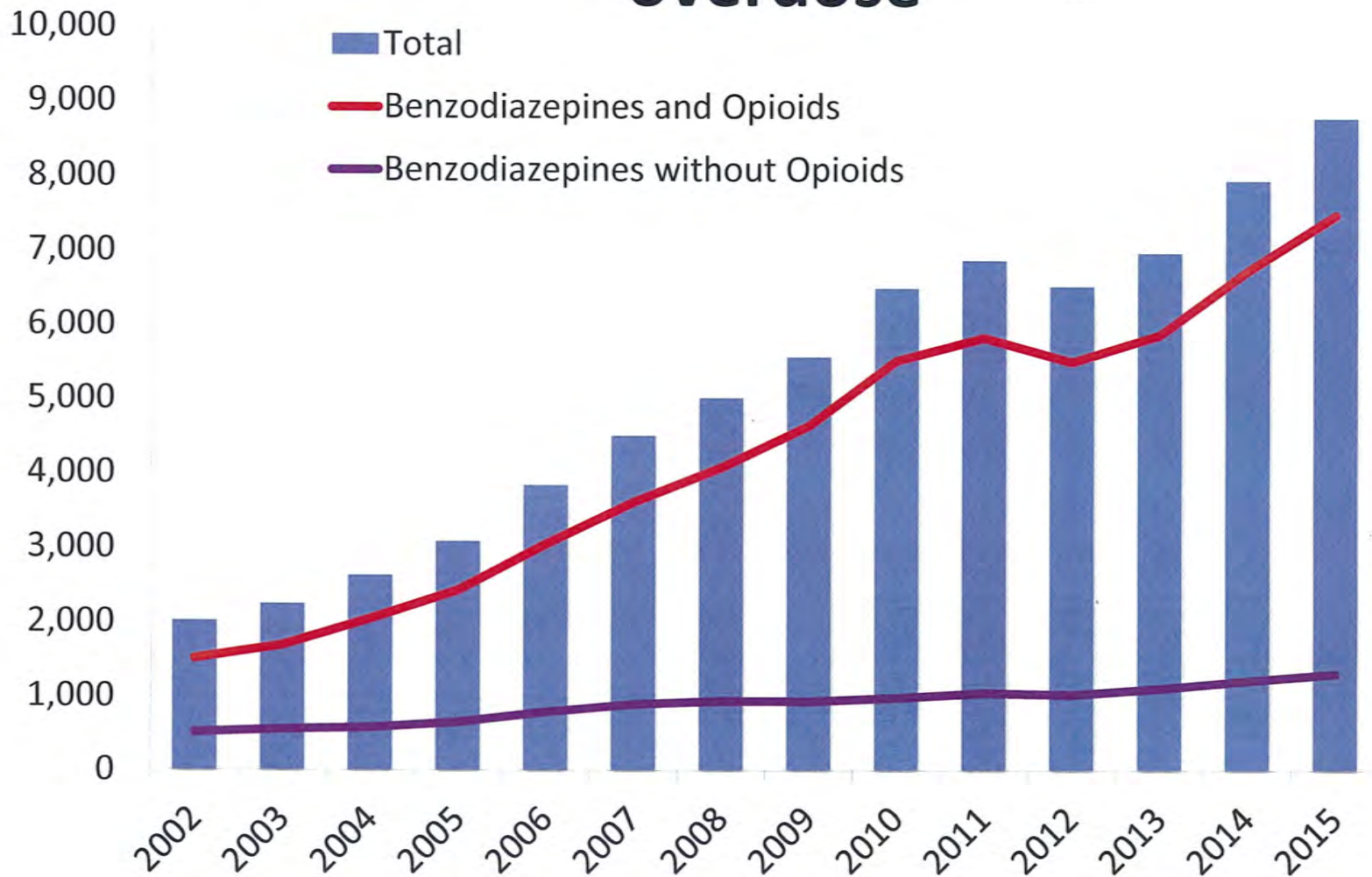
Year	All drug overdose deaths		Heroin		Natural and semisynthetic opioids		Methadone		Synthetic opioids excluding methadone		Cocaine		Psychostimulants with abuse potential	
	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent
2010	38,329	100	3,036	7.9	10,943	28.6	4,577	11.9	3,007	7.8	4,183	10.9	1,854	4.8
2014	47,055	100	10,574	22.5	12,159	25.8	3,400	7.2	5,544	11.8	5,415	11.5	4,298	9.1
2015	52,404	100	12,989	24.8	12,727	24.3	3,301	6.3	9,580	18.3	6,784	12.9	5,716	10.9

NOTES: Deaths are classified using the *International Classification of Diseases, Tenth Revision*. Drug overdose deaths are identified using underlying cause-of-death codes X40–X44, X60–X64, X85, and Y10–Y14. Drug overdose deaths involving selected drug categories are identified by specific multiple-cause-of-death codes: for heroin, T40.1; natural and semisynthetic opioids, T40.2; methadone, T40.3; synthetic opioids excluding methadone, T40.4; cocaine, T40.5; and psychostimulants with abuse potential, T43.6. Categories are not mutually exclusive because deaths may involve more than one drug. The percentage of drug overdose deaths lacking information on the specific drugs involved varied by year: 25% in 2010, 19% in 2014, and 17% in 2015.

SOURCE: NCHS, National Vital Statistics System, Mortality.



Opioid involvement in benzodiazepine overdose

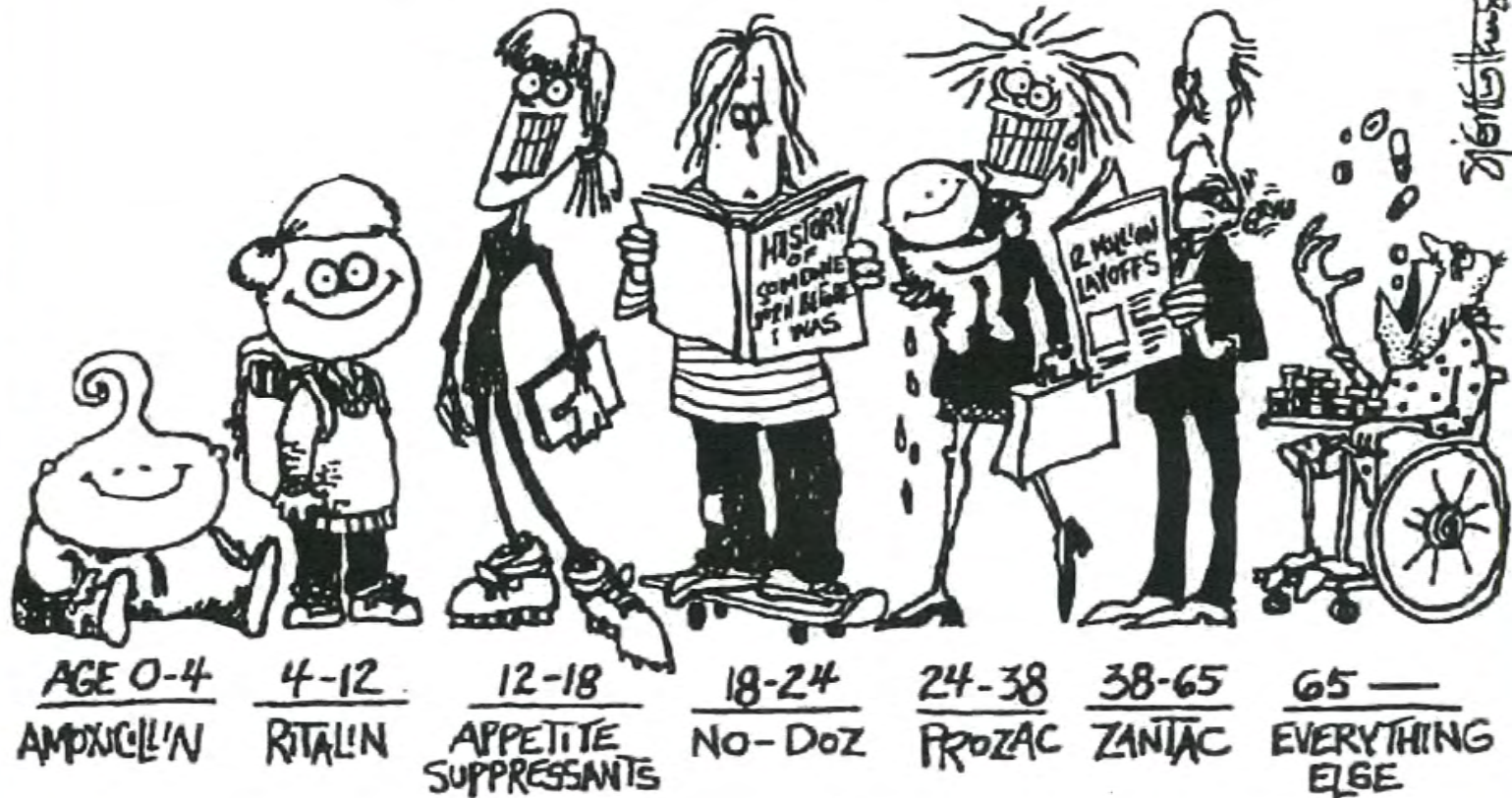


Source: National Center for Health Statistics, CDC Wonder



DRAWINGBOARD / SIGNE

DRUG-FREE AMERICA





How did we get here?





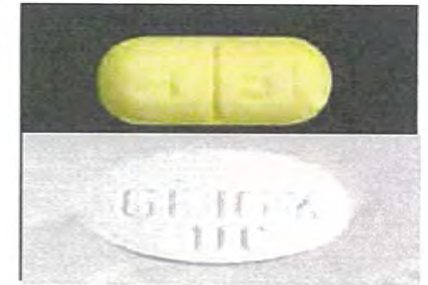
The 1960s/70s/80s



Uppers - Amphetamines



Quaalude



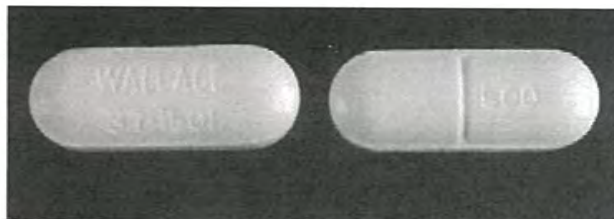
"Ts and Blues"



Downers - Barbiturates



Hydromorphone

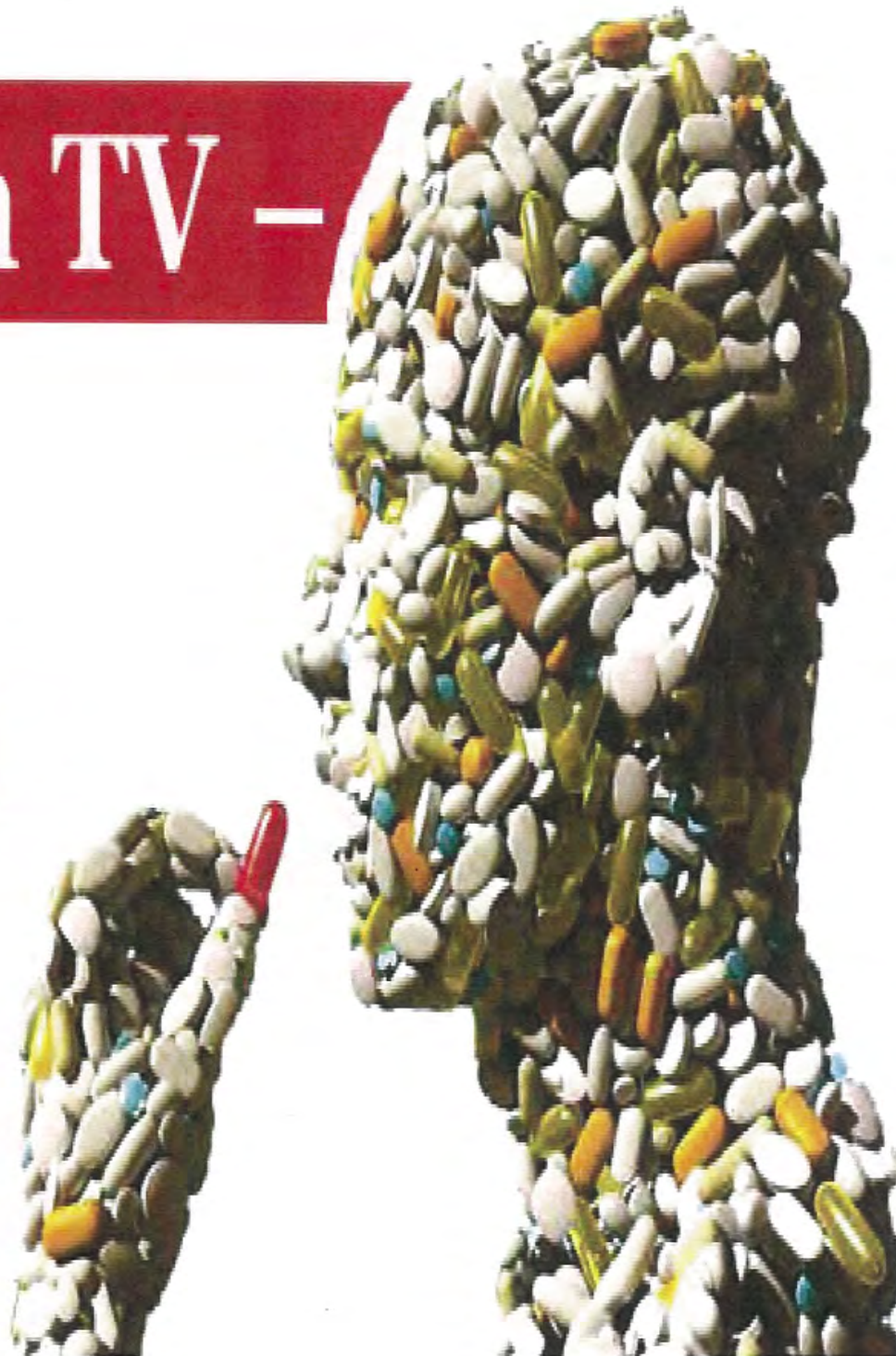


Meprobarnate



Rx Drug Ads on TV – Educational or Influential ?

Overweight? Suffering from anxiety or erectile dysfunction? Well, relief is just a prescription pill away according to the endless television ads promoting prescription drugs.





10 mg



20 mg



40 mg



80 mg



160 mg



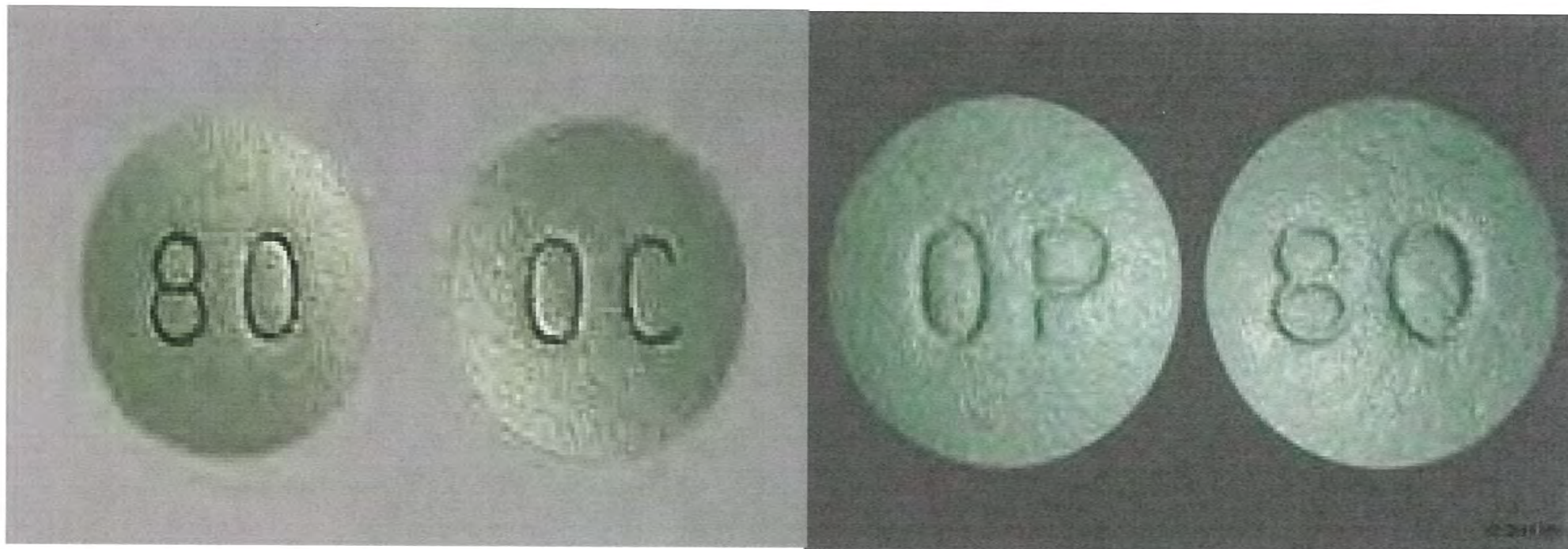
**The
1990s**

OxyContin® Tablets
(oxycodone hydrochloride controlled-release)

Oxycontin

- OxyContin controlled release formulation of Schedule II oxycodone
 - The controlled release method of delivery allowed for a longer duration of drug action so it contained much larger doses of oxycodone
 - Abusers easily compromised the controlled release formulation by crushing the tablets for a powerful morphine-like high
 - 10, 20, 40, 80mg available
- Effects:
 - Similar to morphine in effects and potential for abuse/dependence
 - Sold in **“Cocktails”** or the **“Holy Trinity”**
 - **Oxycodone, Soma[®] and Xanax[®]**
- Street price: Approx. \$80 per 80mg tablet

Oxycodone HCL CR (OxyContin®) Reformulation



NOTE: New formulation introduced in 2010 made it more difficult to circumvent for insufflation (snorting) or injection. Does nothing to prevent oral abuse.

Caused large drops in sales when the reformulation when into effect.



“Primum non nocere”
"First, do no harm"



Drugs of Abuse



*U.S. Drug Enforcement Administration
Diversion Control Division*

Most commonly prescribed prescription medicine?

Hydrocodone/acetaminophen

Hydrocodone

- Hydrocodone / Acetaminophen (toxicity)
- Similarities:
 - Structurally related to codeine
 - Equal to morphine in producing opiate-like effects
- Brand Names: Vicodin[®], Lortab[®], Lorcet[®]
- **October 6, 2014 moved to SCHEDULE II**
- **“Cocktail” or “Trinity”**
 - Hydrocodone (opioid)**
 - Soma[®] / carisoprodol (Schedule 4 muscle relaxant)**
 - Alprazolam / Xanax[®] (Benzo)**

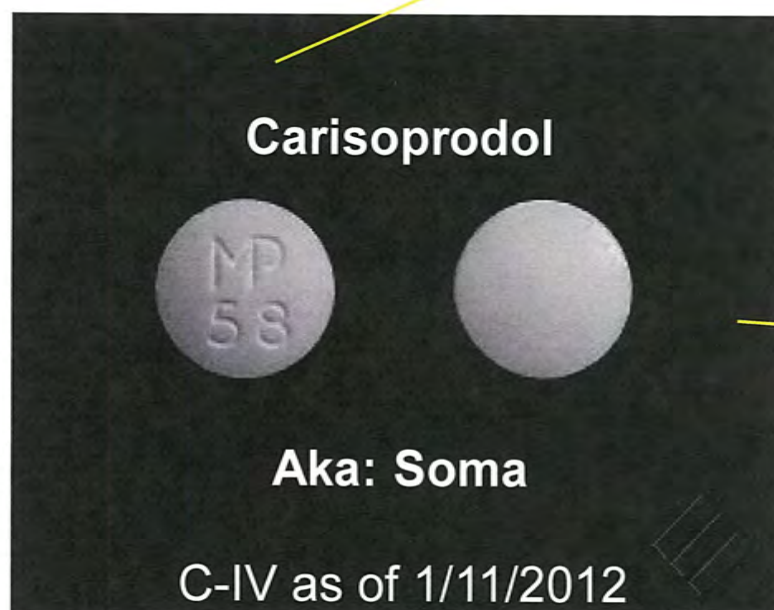
Street prices: \$2 to \$10 per tablet depending on strength & region



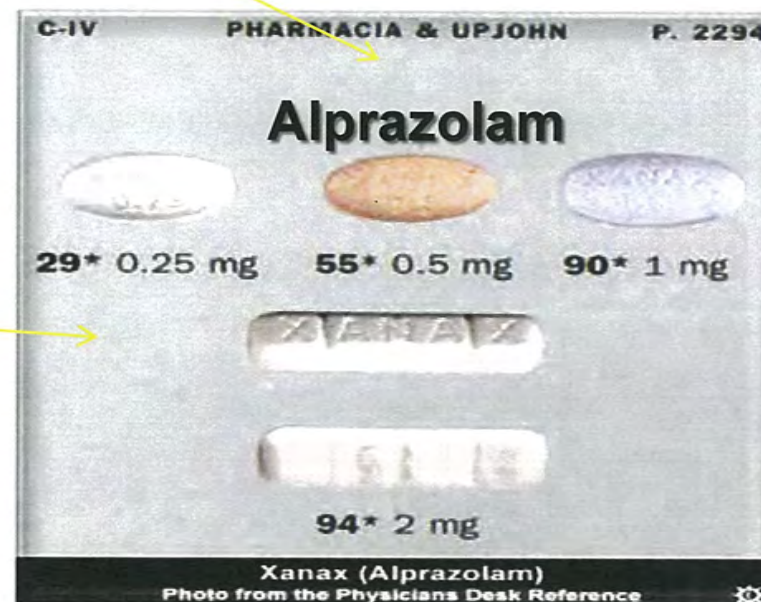
The Trinity Cocktail



Opiate



Muscle Relaxant



Benzodiazepine

jackie jones

Bluelight Crew

Jackie Jones

Join Date: Jul 2008

Location: A spoonful of sugar helps the medicine go down.

Posts: 5,589

20-02-2014 15:32

#19

ZohydroER
(hydrocodone bitartrate)
EXTENDED-RELEASE CAPSULES

1st

Oral, Extended Release
Hydrocodone without
Acetaminophen for Treating
Chronic Pain

PDUFA Date March 1, 2013



- potent extended release formulation
- straight-up hydrocodone/no acetaminophen
- Opiate: 5-10 times stronger than Vicodin
- Manufactured by Zogenix
- Approved by FDA 10/25/2013
- can last up to 12 hours of pain relief per dose

REPLY

QUOTE

📄

Bigfanofthemdrugs

Moderator

Drug Culture
Cannabis Discussion



Join Date: Mar 2012

Location: The Limbic System

20-02-2014 20:20

#20

Idk what you guys are tripping about, I'm stoked to get in on some of that, hydrocodone is one of my favorite opioids. It's just as euphoric as oxy IMO.

Oxymorphone Extended Release

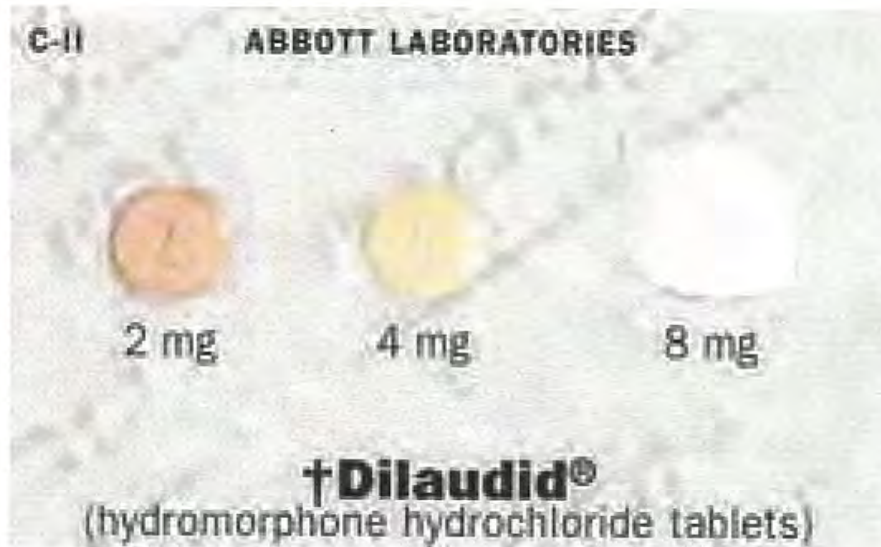
Opana ER[®] (Schedule II)

➤ Opana ER[®] - (Schedule II)

- Treats constant, around the clock, moderate to severe pain
- Becoming popular and is abused in similar fashion to oxycodone; August 2010 (Los Angeles FD TDS)
- Slang: Blues, Mrs. O, **Octagons**, Stop Signs, **Panda Bears**
- **Street: \$10.00 – \$80.00**



Hydromorphone



- Opioid
- Used for moderate to severe pain
- 8 times stronger than morphine
- Recreationally used as heroin
- Best consumed intravenously



****In 2008, there were over 14,000 hydromorphone overdose deaths in the US.***

Methadone- 5mg &10mg



Methadone 40 mg



NDC 0406-0540-34 100 TABLETS

METHADOSE™
Dispersible Tablets **C II**
(Methadone Hydrochloride
Tablets for Oral Suspension USP)

40 mg

Each tablet contains:
Methadone Hydrochloride USP..... 40 mg
Rx only

Mallinckrodt

Usual Dosage:
See accompanying literature for dosage.

Keep tightly closed.

Dispense in a tight container (USP) with a child-resistant closure.

Store at 20° to 25°C (68° to 77°F) (see USP Controlled Room Temperature).

Do not accept if seal over bottle opening is broken or missing.

Mallinckrodt Inc.,
Hazelwood, MO 63042 USA.

COVIDIEN™

Other Opiates of Interest



Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 100 mg



Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 15 mg



Trade Name: MS Contin
Controlled Ingredient: morphine sulfate, 30 mg



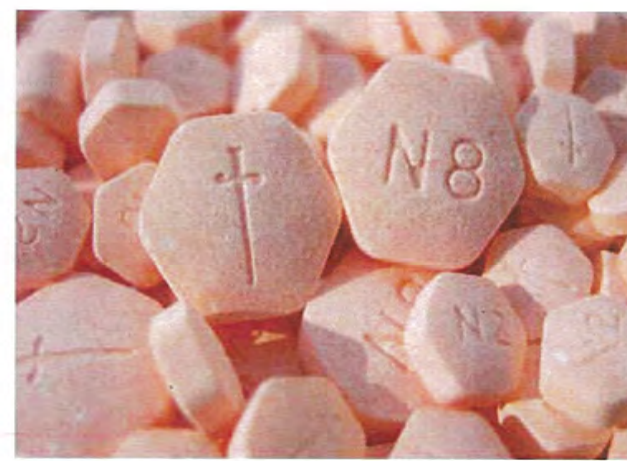
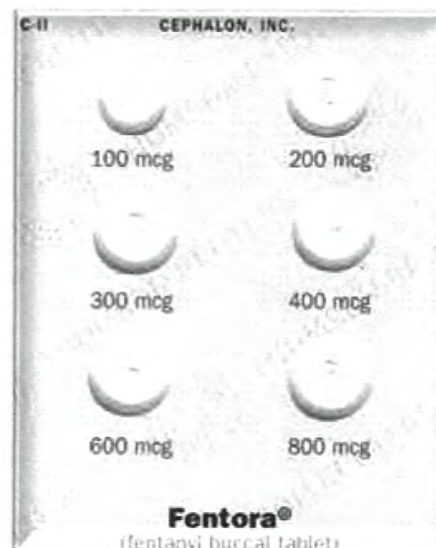
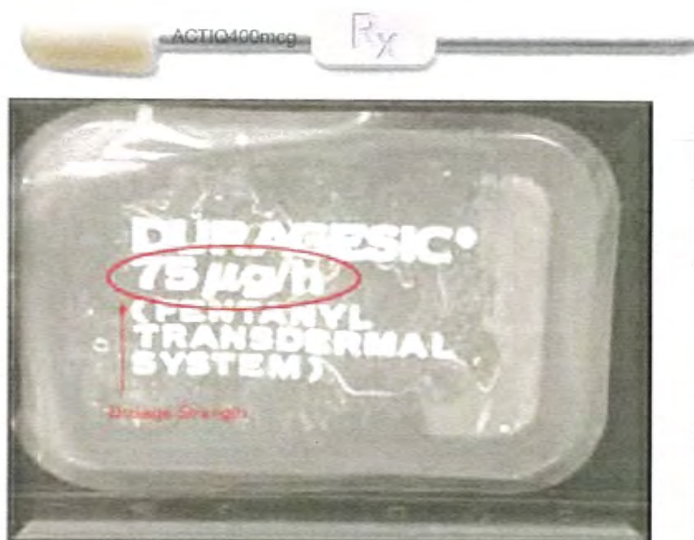
Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 30 mg



Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 100 mg



Trade Name: Oramorph SR
Controlled Ingredient: morphine sulfate, 60 mg



Our Youth



Generation RX



Most Frequent Method of Obtaining a Pharmaceutical Controlled Substance for Non Medical Use

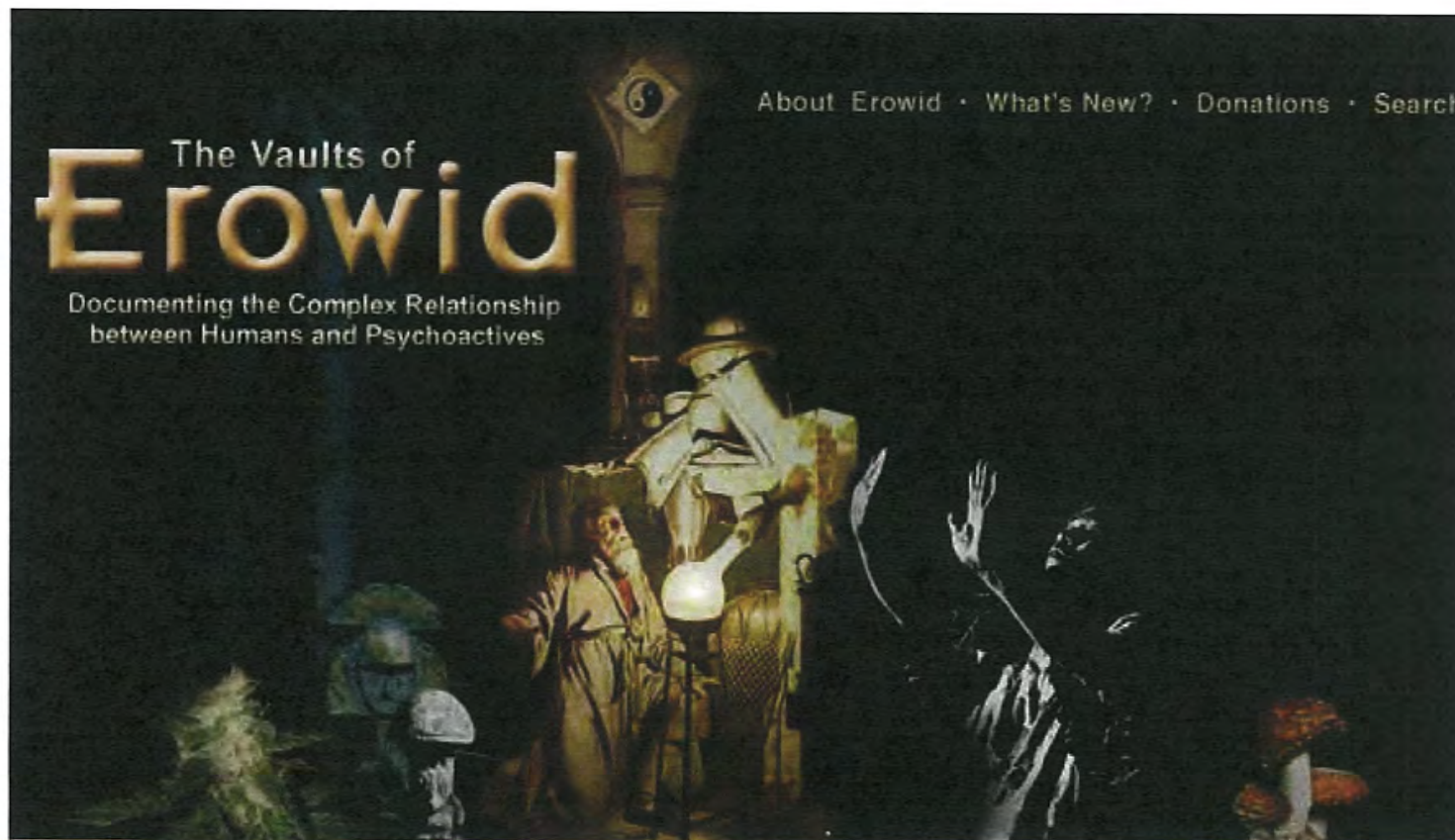
Friends and Family...For Free!!





Where else do our kids get their information from?

www.erowid.org



Where do kids get their information from?

www.bluelight.org

The screenshot shows the BlueLight website interface. At the top, there's a navigation bar with links for Home, Forum, What's New?, and Wiki. A search bar is also present. Below the navigation bar, a banner for "HARM REDUCTION WORKSHOP with BLUELIGHT PSYCHEDELIC SCIENCE 2013" is displayed, dated April 10th and 11th, 2013, in Oakland, California. The main content area features a "THE FRONT PAGE" section with a headline: "A Letter to BlueLight and MAPS Forum members From Brad Burge (MAPS) and Sebastians_Ghost (BL)". The article, published on 05-04-2013 at 06:57, discusses a major collaboration between BlueLight.ru and the Multidisciplinary Association for Psychedelic Studies (MAPS). It mentions that the MAPS Forum will be migrating to BlueLight.ru and that the new MAPS Forums will be launched shortly before the Psychedelic Science 2013 symposium in mid-April. To the left of the main content, there are two sidebars: "Features" and "Forums". The "Features" sidebar lists links to the BlueLight Wiki, Blogs, BlueLight Mobile, Staff List, and Twitter. The "Forums" sidebar lists various discussion topics such as Focus Forums, Drug FAQs, Ecstasy Discussion, Cannabis Discussion, Steroid Discussion, Psychedelic Drugs, Other Drugs, Drug Discussion, Drug Studies, Drugs in the Media, Basic Drug Discussion, and Advanced Drug Discussion, along with regional forums for Australia & Asia, Europe & Africa, and North America & South America.

Case: 1:17-md-02804-DAP Doc #: 3149-9 Filed: 02/03/20 28 of 90. PageID #: 488114

Where do kids get their information from?

www.bluelight.org

← → ↻ 🏠 📄 www.bluelight.ru/vb/

Google BlueLight

User Name Password Log in Help Register
Remember Me?

BLUELIGHT

HARM REDUCTION WORKSHOP with BLUELIGHT
PSYCHEDELIC SCIENCE 2013 APRIL 10TH REGISTER NOW
OAKLAND MARRIOTT CITY CENTER • CALIFORNIA

Home Forum What's New? Wiki

The Front Page

If this is your first visit, be sure to check out the FAQ.
You may have to register before you can post: click the register link above to proceed. To start viewing messages, select the forum that you want to visit from the selection below.


Features

- BlueLight Wiki Our own Wiki project
- Blogs Blogs from our members
- BlueLight Mobile Use BlueLight on the go!
- Staff List Contact our staff members
- Twitter Follow us on Twitter

THE FRONT PAGE

A Letter to BlueLight and MAPS Forum members From Brad Burge (MAPS) and Sebastians_Ghost (BL)

by Sebastians_ghost Published on 05-04-2013 06:57



It is with great pride and enthusiasm that we announce today a major collaboration between BlueLight.ru and the Multidisciplinary Association for Psychedelic Studies.

Through the efforts of Brad Burge, MAPS' Director of Communications, Rick Doblin, MAPS' Founder and Executive Director, Sebastians_Ghost, and The_Love_Bandit of BlueLight.ru, we will soon undertake an exciting partnership to reinvigorate the MAPS forum and increase opportunities for public education about psychedelic science and medicine. The existing plaintext email MAPS Forum will be migrating to BlueLight.ru, the world's leading drug information website. We're aiming to unveil the new MAPS Forums on BlueLight shortly before the Psychedelic Science 2013 symposium in mid-April.

In the coming weeks, the MAPS Forum will no longer be linked from maps.org. Instead, MAPS will provide a link to the new MAPS Forum hosted at BlueLight. MAPS will work closely with BlueLight to encourage public participation in our new "home" at BlueLight.ru as the migration of the MAPS Forum topics is completed.

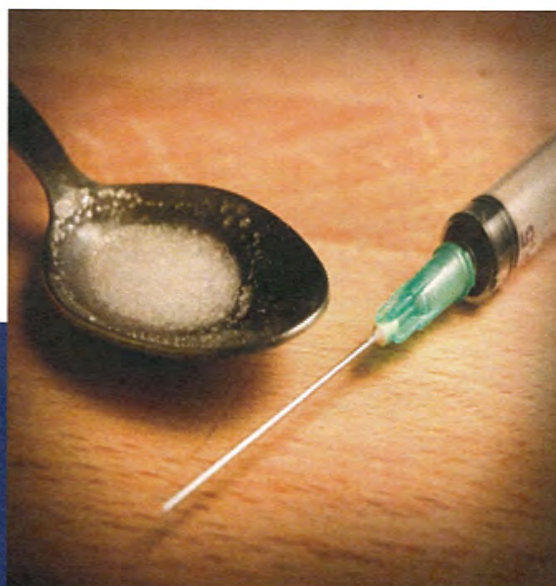
Forums

Focus Forums	Australia & Asia
Drug FAQs	Australian Drug Discussion
Ecstasy Discussion	Australian Social & Events
Cannabis Discussion	
Steroid Discussion	Europe & Africa
Psychedelic Drugs	European Drug Discussion
Other Drugs	European Events
Drug Discussion	North America & South America
Drug Studies	North & South American
Drugs in the Media	Social & Drug Discussion
Basic Drug Discussion	North & South American
Advanced Drug	Events

start BlueLight - The Front ...

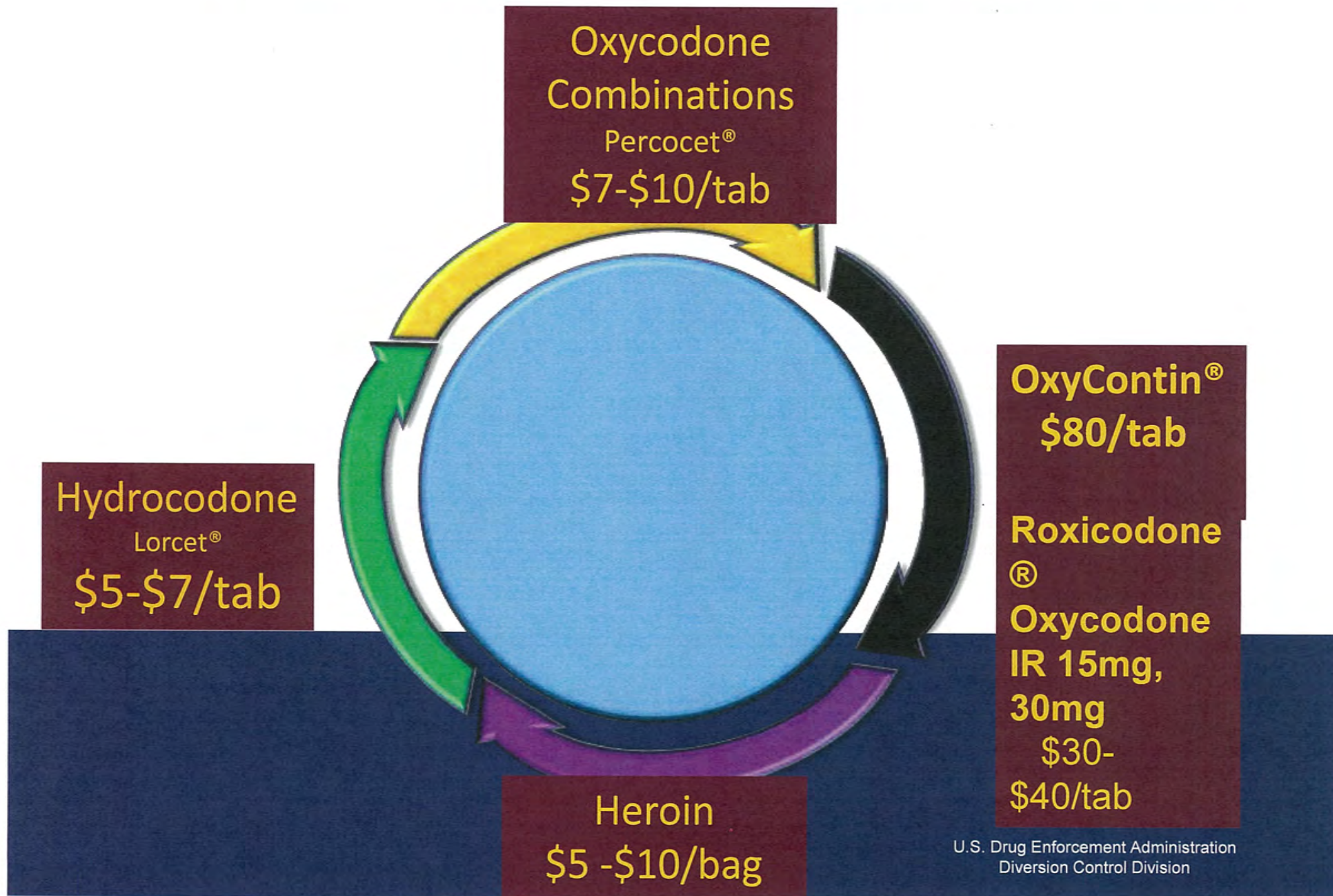


Pills v. Heroin



U.S. Drug Enforcement Administration
Diversion Control Division

Circle of Addiction & the Next Generation



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The Examiner
WASHINGTON
WEDNESDAY, DECEMBER 5, 2012

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'Liaisons Dangereuses'
New approach to classic P. 19

Playoff possibilities
Schedule favors Skins P. 35

Cooling down



POLITICS

Stalemate on 'cliff'

Sides stop talking;
Obama's rate hikes
may be flexible. P. 13

LOCAL

FBI analyst husted

Heroin use spikes in area suburbs

Pill addicts risk deadly drug



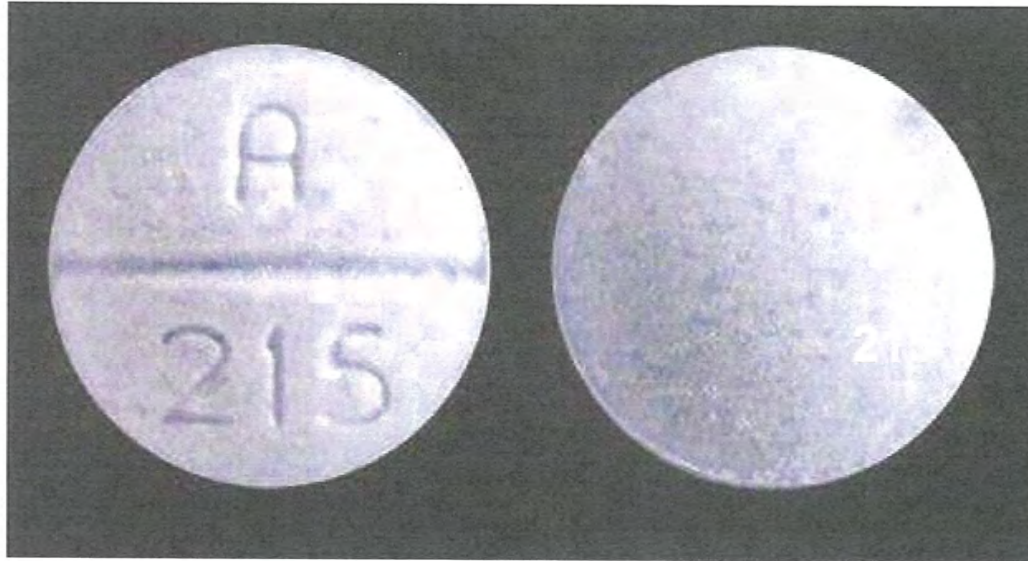
Community Impact?

Heroin trafficking organizations relocating to areas where prescription drug abuse is on the rise

Heroin traffickers pave the way for increasing crime and violence

Law enforcement and prosecutors eventually fighting the problem on two fronts (prescription opiate diversion and heroin distribution) further depleting resources

Communities suffer



Pharmaceutical Oxycodone 30mg

Heroin Seizure



SECTIONS



TRAFFIC



WATCH

NEWS

COPS: PHOTOS OF BOY WITH PASSED-OUT ADULTS SHOW DRUG SCOURGE

Share

Email



Police in East Liverpool, Ohio released these images they say to illustrate the impact of the heroin and painkiller epidemic. (City of East Liverpool, Ohio/Facebook)

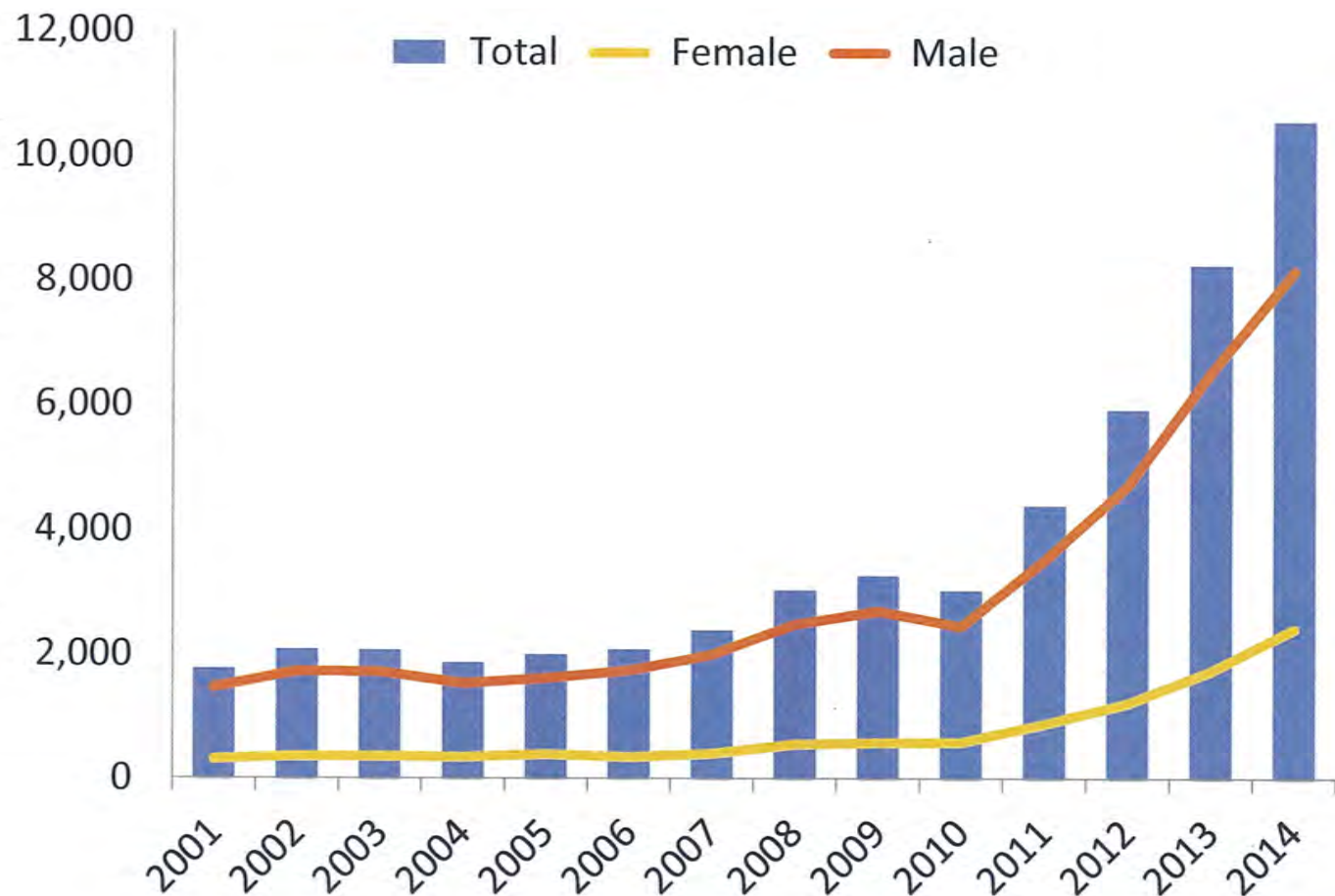


Scope of the Problem

CDC (2016):

Heroin deaths
more than triple
between 2010-2014

"This increase : . .
has been shown to
be closely tied to
opioid pain reliever
misuse and
dependence."



Source: National Center for Health Statistics, CDC Wonder



Opiates and Heroin

- 4 out of 5 recent heroin users initiated used after using prescription opioids non-medically.¹
- The recent heroin abuse rate is 19 times higher among those who reported prior non-medical use of pain relievers than among those who did not report such use.²
- Overdose deaths from heroin abuse have more than doubled since 2010.³

¹NIDA, June 2015

²SAMHSA, August 2013

³NIDA, February 2015



Violence



U.S. Drug Enforcement Administration
Diversion Control Division



Starting the year with a bang

Saranac Hale Spencer, The News Journal 12:36 a.m. EST January 4, 2016



(Photo: DELAWARE STATE POLICE)

A 26-year-old Lewes man threatened to detonate explosives he said were strapped to his body if a pharmacist at a Walgreens near Magnolia didn't give him prescription drugs, according to state police.

The man, Curtis Kuhn, didn't actually have explosives strapped to his body, according to police.

Kuhn went into the pharmacy at about 9:30 a.m. on Saturday and put a note on the counter demanding Percocet and Xanax – he told the pharmacist that he had explosives strapped to his body and he was being forced to commit the robbery by someone who was sitting in a car in the parking lot, according to police.

When officers arrived shortly after that, they took Kuhn into custody without incident and found that he had no explosives and there was no car fitting his description in the parking lot, according to police.

Kuhn was charged with first-degree attempted robbery, attempted theft of a controlled substance and two counts of terroristic threatening. He was arraigned and sent to Vaughn Correctional Center near Smyrna for lack of \$27,000 secured bond and



18



3





Violence Related to Controlled Substance Pharmaceuticals

NEW YORK POST Page Six
THURSDAY, JUNE 23, 2012 / 7 months, 46 weeks, 5 days
METRO EDITION www.nypost.com \$1.00

ASSASSIN



1. Ready for mayhem, the assassin sneaks through the door.
2. Cap in his right hand, he walks easily through an aisle.
3. He pulls his cap over his face as he leaves the store.
4. Now a mass murderer, he walks out into the sunlight.

Chilling anatomy of drugstore massacre

He never gave them a chance. The cold-blooded killer who massacred four people in a Long Island pharmacy methodically shot each victim, shocking, step-by-step surveillance footage of the slaughter revealed yesterday.

PAGES 4-5

NEW YORK POST Page Six
THURSDAY, JUNE 23, 2012 / 7 months, 46 weeks, 5 days
METRO EDITION www.nypost.com \$1.00

DRUGSTORE MASSACRE

Husband and wife busted in Rx-slay horror



PAIN KILLER

David Letter is the man caught on video wearing a fake beard (top) who slaughtered four people in a pharmacy to fund his wife Martina's addiction, cops said yesterday.

PAGES 4-5



Prescription Drug Abuse is driven by

Indiscriminate Prescribing Criminal Activity

Many Patients Share Medication prescribed

Two new U.S. studies shed light on opioid epidemic

- **1. University of Pennsylvania Dental School Study:**

***More than half of the narcotics prescribed for wisdom teeth removal go unused...findings suggest that more than 100 million pills prescribed go unused...leaving the door open for possible misuse or abuse.**

Source: <https://www.pennmedicine.org/news/news-releases/2016/september/100-million-prescription-opioid>

- **2. John Hopkins Study:**

- +60% had leftover opioids they hung on for “**future use**”

- 20% **shared** their medications

- 8% likely will share w/ **friend**

- 14% likely will share w/ **relative**

- 10% **securely lock their medication**

https://www.nlm.nih.gov/medlineplus/news/fullstory_159336.html



CDC Guidelines for Prescribing Opioids for Chronic Pain

- Clinical Reminders:
 - **Opioids are not first-line or routine therapy for chronic pain**
 - Establish and measure goals for pain and function
 - Discuss benefits and risks and availability of non opioid therapies with patient



CDC Guidelines for Prescribing Opioids for Chronic Pain

- Use immediate-release opioids when starting
- *Start low and go slow*
- When opioids are needed for acute pain, prescribe no more than needed
- Do not prescribe ER/LA opioids for acute pain
- *Follow-up and re-evaluate risk of harm*; reduce dose or taper and discontinue if needed



CDC Guidelines for Prescribing Opioids for Chronic Pain

- Evaluate risk factors for opioid-related harms
- ***Check PDMP*** for higher dosages and prescriptions from other providers
- ***Use urine drug testing to identify prescribed substances and undisclosed use***
- Avoid concurrent benzodiazepine and opioid prescribing
- Arrange treatment for opioid use disorder if needed

Survey of Long-Term Painkiller Users

- Majority say their doctor talked about possibility of addiction or dependence – **61% say there was no discussion about plan to get them off.**
- Majority say they used the drugs to relieve pain. Other major reasons for taking them:
 - 20% - ‘for fun or get high’
 - 14% - “to deal with day-to-day stress”
 - 10% - “to relax or relieve tension”
- Other Findings:
 - 34% admit being dependent or addicted
 - 17% have taken painkillers that were not specifically prescribed for them
 - 14% have given their painkillers to a family member or friend
 - 20% know or suspect someone was using, taking or selling their painkillers



Criminal Activity



U.S. Drug Enforcement Administration
Diversion Control Division



United States V. Alvin Yee, M.D.

Dr. Alvin Yee



U.S. Drug Enforcement Administration
Office of Diversion Control





United States V. Alvin Yee, M.D.

Dr. Yee primarily met with his “patients” in Starbucks cafes throughout Orange County, California.

He would see up to a dozen patients each **night** between **7:00 and 11:00 p.m.** and wrote these “patients” prescriptions, primarily for opiates, in exchange for cash.

Yee pled guilty to distributing millions of dollars in ***oxycodone, oxymorphone, hydrocodone, hydromorphone, Adderall® and alprazolam*** outside the course of professional practice and without a legitimate medical purpose.





United States V. Alvin Yee, M.D.

CURES Data (PMP)

During a one-year time period, Yee wrote prescriptions for a total of **876,222 dosage units** of all medications combined.

52% of all prescriptions (458,056 dosage units) written by Yee were for oxycodone (92%-30mg) during the one-year period.

96% - oxycodone, hydrocodone, alprazolam, hydromorphone, and oxymorphone.

Almost half of **Yee's patients** were **25 and under**.





Legal Obligations of DEA Registrants



U.S. Drug Enforcement Administration
Diversion Control Division



Effective Controls

- All applicants and registrants shall provide effective controls and procedures to guard against theft and diversion of controlled substances.
- In order to determine whether a registrant has provided effective controls against diversion, the Administrator shall use the security requirements set forth in §§ 1301.72-1301.76 as standards for the physical security controls and operating procedures necessary to prevent diversion.

21 CFR § 1301.71(a)



Suspicious Orders

Non-practitioners of controlled substances

“The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances...Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.”

21 CFR § 1301.74(b)

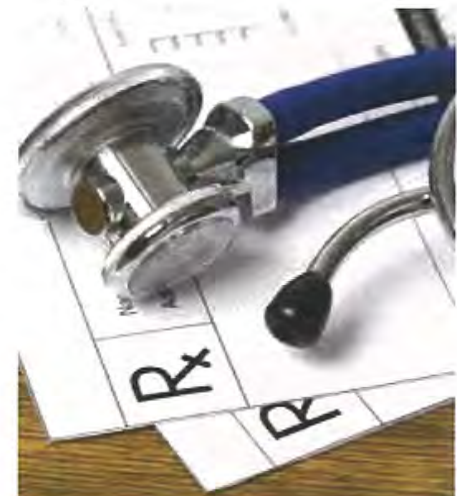


Prescriptions

A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.

21 CFR § 1306.04(a)

United States v Moore 423 US 122 (1975)





Corresponding Responsibility by Pharmacist

- A pharmacist, by law, has a corresponding responsibility to ensure that prescriptions are legitimate.
- When a prescription is presented by a patient or demanded to be filled for a patient by a doctor's office, a pharmacist is not obligated to fill the prescription!!!





Corresponding Responsibility by Pharmacist

The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription.

21 CFR § 1306.04(a)





The Last Line of Defense



U.S. Drug Enforcement Administration
Diversion Control Division



Potential Red Flags

- Many customers receiving the same combination of prescriptions; ***cocktails***
- Many customers receiving the same strength of controlled substances; no individualized dosing: ***multiple prescriptions for the strongest dose***
- Many customers ***paying cash*** for their prescriptions
- ***Early refills***
- Many customers with ***the same diagnosis codes*** written on their prescriptions;
- Individuals driving ***long distances to visit physicians*** and/or to fill prescriptions;



Potential Red Flags continued

Customers *coming into the pharmacy* in groups, each *with the same prescriptions issued by the same physician*; and

Customers with prescriptions for controlled substances written by physicians not associated with pain management (i.e., pediatricians, gynecologists, ophthalmologists, etc.) - **Check Dr. Specialty**


Overwhelming proportion of prescriptions filled by pharmacy are controlled substances


Pharmacist did not reach out to other pharmacists to determine why they were not filling a particular doctor's prescription









Verification of legitimacy not satisfied by a call to the doctors office



www.nabp.net


**NABP**
NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Search the site 


       

HOME ABOUT PROGRAMS PUBLICATIONS NEWS MEETINGS CONTACT

AGENCY OF PHARMACY MEMBERS PHARMACEUTICALS CLIENTS TECHNICIANS OFFICE PHARMACY ATTORNEYS COLLABORATION


 **QUESTION? CHAT IS AVAILABLE**


Meet the NABP Executive Committee




The 2015-2016 NABP Executive Committee, including President Edward O. McInley, MBA, RPh, were inaugurated at the 111th Annual Meeting. [Learn More](#)

2015-2016 Executive Committee


 Chairman - [Edward O. McInley, MBA, RPh](#)

 President - [Edward O. McInley, MBA, RPh](#)

 President Elect - [Mik Warrick, MBA, RPh](#)

Do You Know What a Doctor Shopper Looks Like?

Americans abuse prescription drugs more than cocaine, heroin, and hallucinogens combined. The "Red Flags" video helps pharmacists identify the warning signs of prescription drug abuse and diversion.





Red Flags for Pharmacists

Verified Pharmacy Program

CPE Monitor

Safe Online Pharmacies

 **NEWSROOM HEADLINES**

 **REBROADCAST**



Who do I call to report a practitioner?

- Local Police, County, State
- State Board of Pharmacy, Medicine, Nursing, Dental
- DEA local office and Tactical Diversion Squad
- Health Department
- HHS OIG if Medicare, Medicaid fraud



DEA's Mission



U.S. Drug Enforcement Administration
Diversion Control Division



Mission

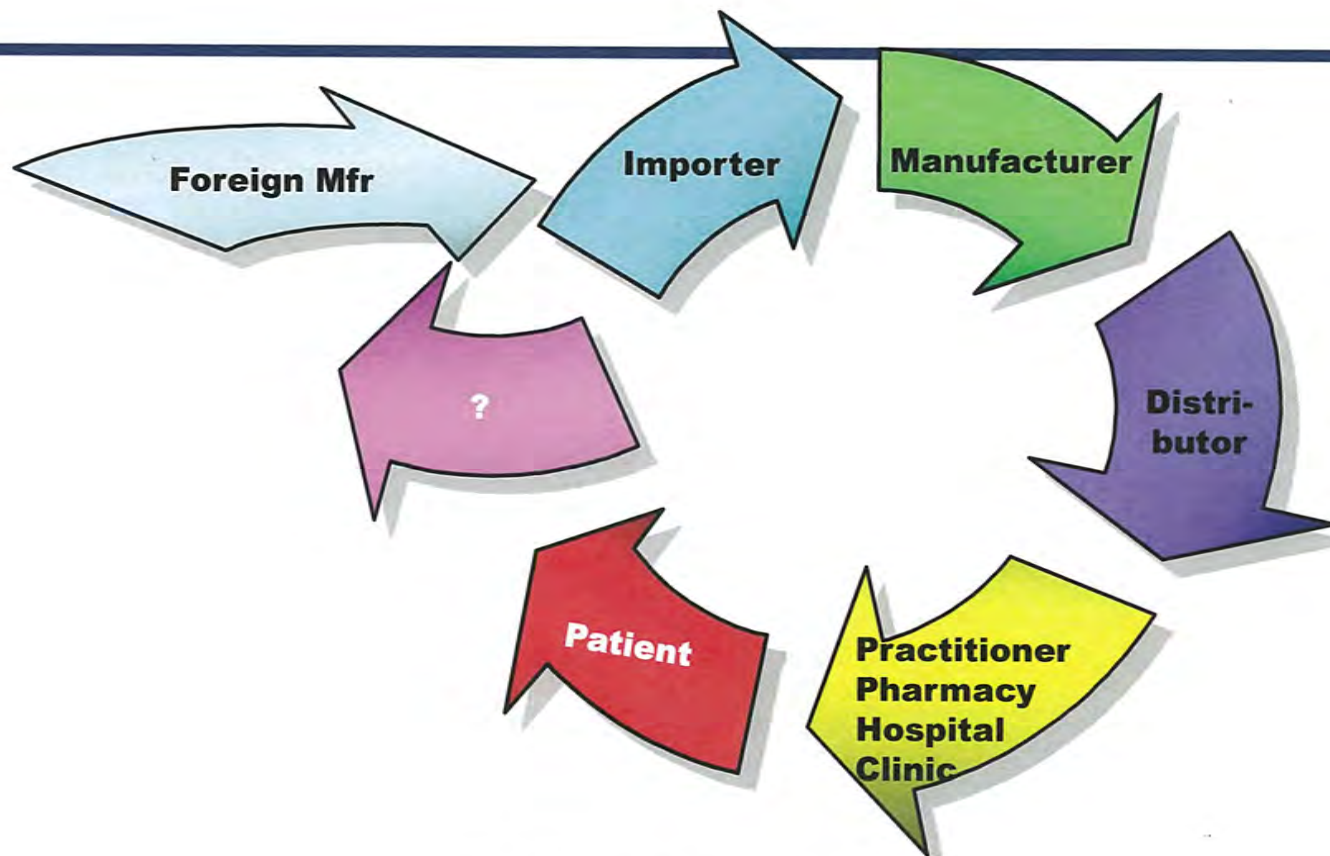
The mission of the Diversion Control Division is to prevent, detect, and investigate the diversion of pharmaceutical controlled substances and listed chemicals from legitimate channels of distribution

while ...

ensuring an adequate and uninterrupted supply of controlled substances to meet legitimate medical, commercial, and scientific needs.



Closed System of Distribution

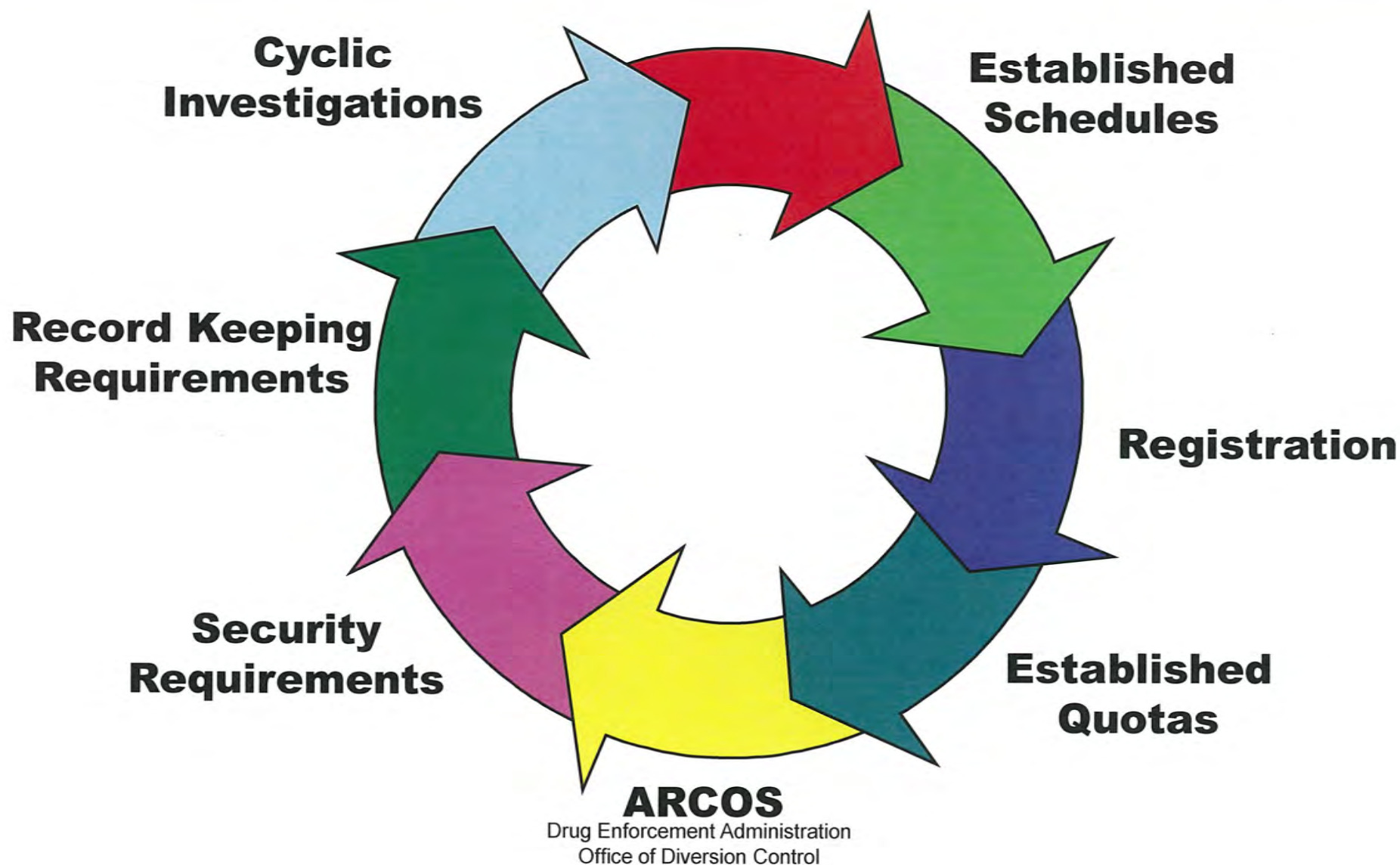


1,677,537 (1/18/2017)

- **Practitioners:** 1,253,249
- **Mid Level Practitioner:** 319,280
- **Retail Pharmacies:** 72,126
- **Hospital/Clinics:** 17,674



Closed System of Distribution





Closed System of Distribution

The DEA is responsible for:

- the oversight of the system
- the integrity of the system
- the protection of the public health and safety

***DEA doesn't regulate the practice of medicine.**



DEA's Response



U.S. Drug Enforcement Administration
Office of Diversion Control



Scheduled Investigations

- DEA has increased the number of registrants to be inspected to ensure compliance with the Controlled Substances Act and its implementing regulations
- DEA has also increased in the frequency of the regulatory investigations
- Verifications of customers and suppliers



Drug Enforcement Administration

360 Degree Strategy





Drug Enforcement Administration

Community Partnerships



- DEA recognizes we cannot arrest our way out of the drug problem – our goal is lasting success in the communities we serve.
- Education and Prevention are key elements for a true 360 Strategy.
- Law enforcement operations provide an opportunity for community empowerment and a jumping off point for education and prevention efforts.



DEA Registrant Initiatives

Distributor Initiative

Educate and inform distributors/manufacturers of their **due diligence responsibilities** under the CSA by **discussing their Suspicious Order Monitoring System**, reviewing their ARCOS data for sales and purchases of Schedules II and III controlled substances, and discussing national trends involving the abuse of prescription controlled substances

Briefings to **99** firms with **309** registrations



DEA Registrant Initiatives

Pharmacy Diversion Awareness Conferences

These conferences are designed to educate pharmacists, pharmacy technicians, and pharmacy loss prevention personnel on ways to address and respond to potential diversion activity.

Completed PDACs**FY
-2011****FY-2016**

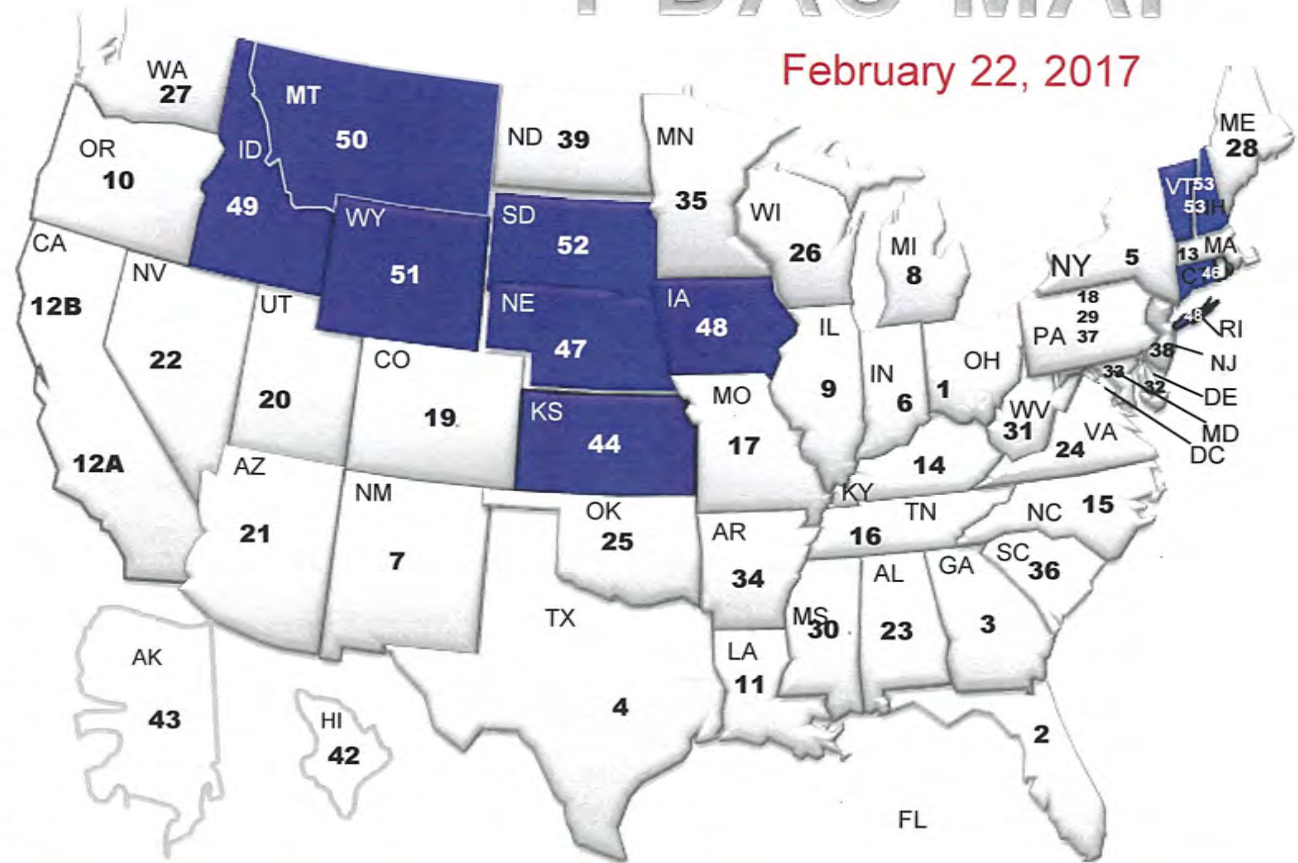
29-Pittsburgh, PA 12/10-11/15
 30-Jackson, MS 1/9-10/16
 31-Charleston, WV 2/27-28/16
 32-Wilmington, DE 3/19-20/16
 33-Towson, MD 4/17-4/18/16
 34-Little Rock, AR 6/11-12-/16
 35-Minneapolis/St. Paul, MN 7/8-9/16
 36-Hilton Head, SC 8/15-16/16
 37-Camp Hill, PA 8/27/16
 38-New Brunswick, NJ 9/18-19/16

FY-2016 Total Attendance**FY-2017**

39-Fargo, ND 10/2/16
 40-Washington, DC 11-19-20/16
 41-Buffalo, NY 12/9-10/16
 42-Honolulu, HI 1/22-23/17
 43-Anchorage, AK 2/10/2017 (61)
 44-Wichita, KS 3/11-12/2017

Attendance

196
 185
 245
 111
 442
 216
 151
 157
 84
 304
 2,091
 68
 414
 239
 114
 109

PDAC MAP**February 22, 2017****FY-2017 PDACs**

44-Kansas – March 11 & 12, 2017
 45-Puerto Rico – March 26 & 27, 2017
 46-Connecticut/Rhode Island – April 2017 (Date TBD)
 47-Nebraska – June 2017 (Date TBD)
 48-Iowa – July 2017 (Date TBD)
 49-Idaho – August 2017 (Date TBD)
 50-Montana – August 2017 (Date TBD)
 51-Wyoming – August 2017 (Date TBD)
 52-South Dakota – September 2017 (Date TBD)
 53-Vermont/New Hampshire – September 2017 (Date TBD)

40 STATES (incl. the D.C.)
CONFERENCES

87 PDAC**45 PR**

Completed PDACs
 Proposed PDACs
 * Repeated State

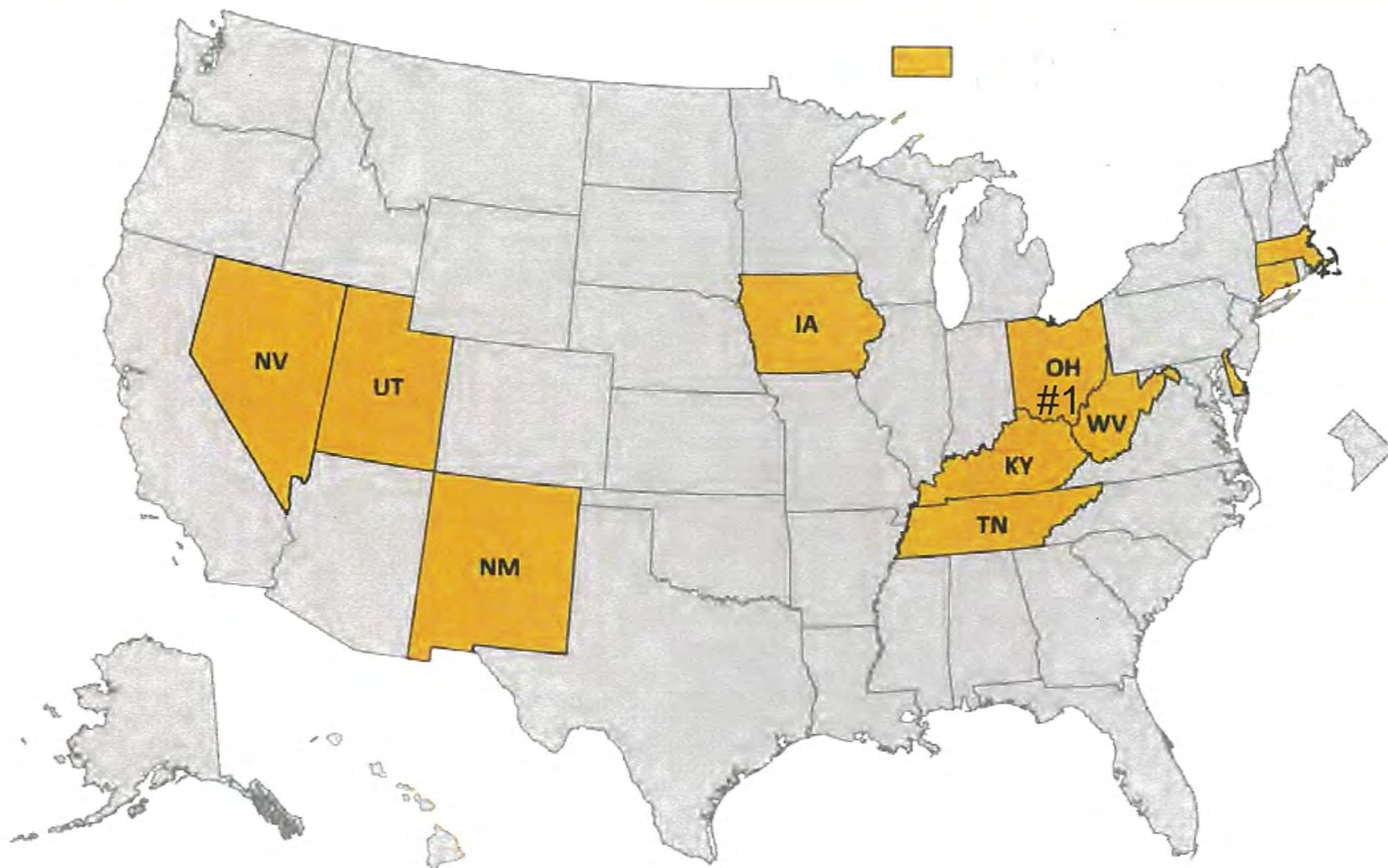


DEA working jointly with FSMB

- The **Federation of State Medical Boards** (FSMB) promotes excellence in medical practice, licensure, and regulation on behalf of 70 state medical and osteopathic Boards across the country in their protection of the public
- DEA and FSMB are currently working on developing strategies to **work more effectively and jointly** on *indiscriminate prescriber* investigations in order to facilitate the administrative process to *take action against those that are a threat to the public health* and welfare quickly, and at the same time not jeopardize a criminal investigation



Since 2011, Eleven States have Passed Legislation Mandating Prescriber Education





Maine

- Second State to Mandate Electronic Prescribing
- Prescribers are required to undergo addiction training every 2 years
- Set cap on daily strength for opioid prescribing:
 - Acute pain – 7 days
 - Chronic pain – 30 days
- Began: **January 2017**



National Take Back Initiative (NTBI)

Got Drugs?

Turn in your
unused or expired
medication for safe disposal
Saturday

Click here
for a collection
site near you.

#13

APRIL 29, 2017

dispose

unused
Rx

DEA

STATE MEDICAL BOARDS

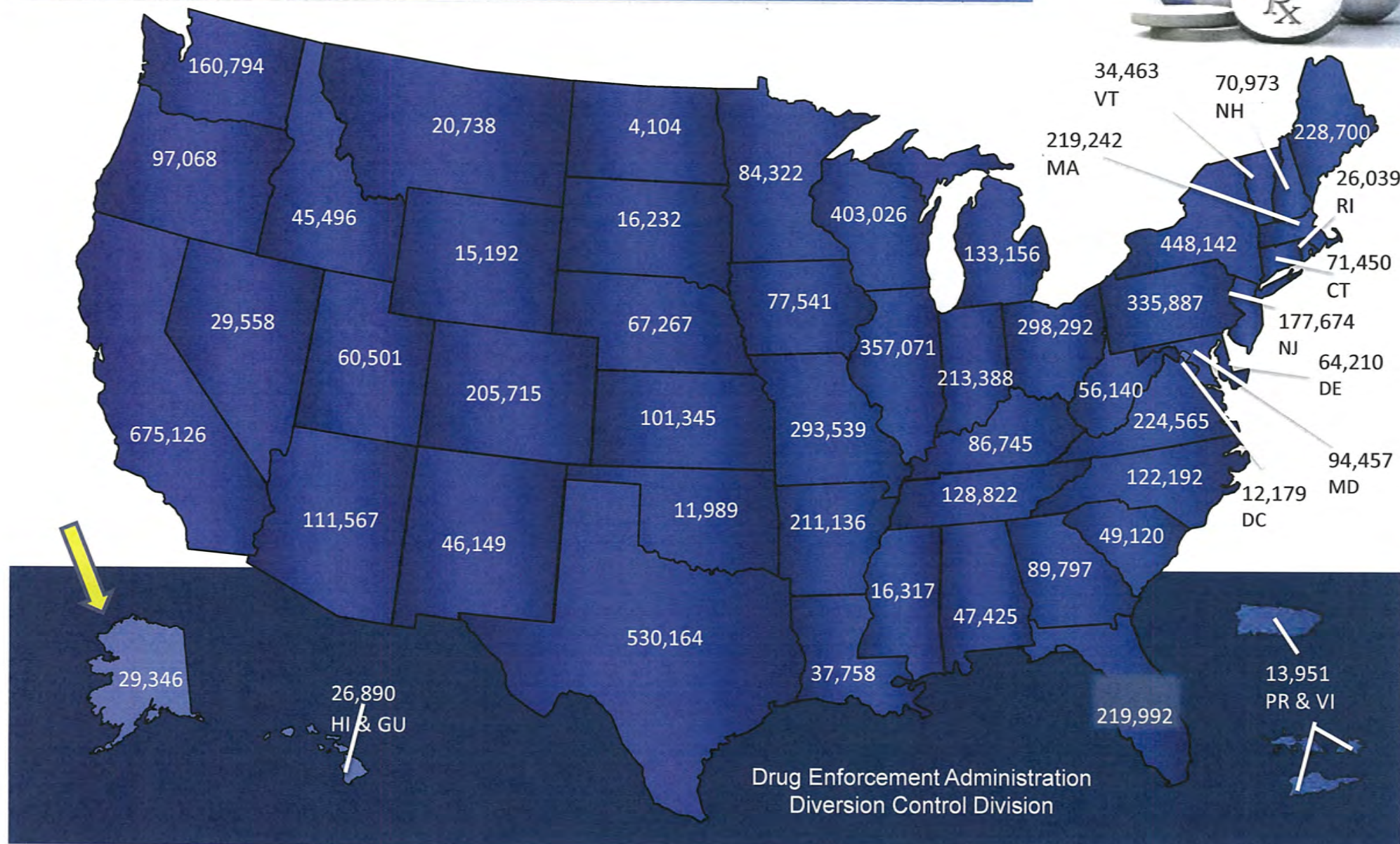
The poster features a large blue pill with the word "dispose" written on it, and a white pill with "Rx" written on it. The background is white with blue and red text. The date "APRIL 29, 2017" is written in large black letters across the center. The number "#13" is in the top right corner. The DEA logo is in the bottom left corner. The text "STATE MEDICAL BOARDS" is in the bottom right corner.

10:00 AM – 2:00 PM

U.S. Drug Enforcement Administration
Diversion Control Division

National Take Back I-XII Totals:

Total Weight Collected (pounds): **7,202,977 pounds (3601 Tons)**





Disposal



U.S. Drug Enforcement Administration
Diversion Control Division



Retail Pharmacies' Disposal - Inventory

For disposals of Retail Pharmacy CS inventory:

- **Incineration and Chemical Ingestion – DEA's acceptable methods of destruction that renders all controlled substances non retrievable**
- **Retail Pharmacies – Use reverse distributors**
- **Use 222s for transfer of Schedule 2 CS**
- **Reverse Distributors will complete the DEA-41: copy may be requested**
- **Present this to Investigators during onsite inspections**



Ultimate User

Ultimate user means as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.”

21 USC § 802(27)

Ultimate user methods of destruction prior to Disposal rule:

- ✓ Disposal in Trash (ONDCP method); or
- ✓ Flushing (FDA opioids and select CSs)
- ✓ National Take-back Event (DEA)
- ✓ Transfer to Law Enforcement
- ✓ (Police Station Receptacles or local Take-back events)





Secure and Responsible Drug Disposal Act of 2010

- CSA amended to provide ultimate users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner

21 USC § 822(f) & (g)

- Participation is voluntary

21 USC § 822(g)(2)

- Registrants authorized to collect:

- Manufacturers
- Distributors
- Reverse Distributors
- Narcotic Treatment Programs
- Hospitals/clinics with an on-site pharmacy
- Retail Pharmacies

21 CFR § 1317.40

Authorized collectors, as registrants, are readily familiar with the security procedures and other requirements to handle controlled substances.



How a registrant becomes a collector?

- Must be registered to handle Schedule 2 CS
- Must request a modification from DEA
(can be in writing or online)
- Request contains:
 1. Registrant's name, address and DEA #
 2. Method of collection:
(receptacle or mail back)
 3. Authorized signature

*No fee for modification

21 CFR 1301.51(b) and (c)



Collection Receptacle

Collection means to receive a controlled substance for the purpose of destruction.

- Places where they can be located:
 1. Inside a collector's registered location
 2. Inside law enforcement location
 3. Inside an authorized LTCF





Collection Receptacles

- Ultimate users *shall* put the substances directly into the collection receptacle.
- Controlled and non-controlled substances may be comingled.
- Collected substances shall not be counted, sorted, inventoried, or otherwise individually handled.
- Registrants (Retail Pharmacies) **shall not dispose of stock or inventory** in collection receptacles.

21 CFR § 1317.75(b) and (c)



Design of Collection Receptacles

- Securely fastened to a **permanent structure**.
- **Securely locked**, substantially constructed container with permanent outer container and removable inner liner.
- Outer container must have **small opening** that **allows for contents to be added**, but **does not allow for removal of contents**.
- Outer container must display a sign **stating only Schedule II-V** and non-controlled substances are acceptable substances.
- **Schedule I** controlled substances **are not permitted to be collected**





Collection Receptacle Inner Liner

- Waterproof, tamper evident and tear resistant
- Removable and sealable without touching content
- Content shall not be viewable from the outside
- Size of liner shall be clearly marked on the outside
- Outside of liner shall have a unique id number

21 CFR 1317.60(a)



Collection Receptacle Location

- Registered location – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
 - LTCF – located in secure area regularly monitored by LTCF employees.
 - Hospital/clinic – located in an area regularly monitored by employees—not in proximity of where emergency or urgent care is provided.
 - NTP – located in a room that does not contain any other controlled substances and is securely locked with controlled access.

21 CFR § 1317.75(d)



Mail-Back Program

Requirements of mail-back program

- Only lawfully possessed schedules II-V controlled substances may be collected
- Controlled and non-controlled substances may be collected together
- **Registrant must have method of on-site destruction**

21 CFR § 1317.70 (b)

DEA Registrant who sells mail-back packages for another registrant is **NOT** required to modify registration as a collector



Pharmaceutical Wastage

Not subject to **21 CFR Part 1317**

- Destruction does not have to be “non-retrievable”
- DEA Form 41 must not be utilized

- Dispensing must be recorded as a record
21 CFR § 1304.22(c)

- Clarification memorandum on DEA website at www.DEAdiversion.usdoj.gov



Questions?



Luis.A.Carrion@usdoj.gov

U.S. Drug Enforcement Administration
Diversion Control Division